**BEST AVAILABLE COPY****DOCKET NO. 02-007 CIP (ANSI01-00057)****PATENT****Customer No. 36029****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: : John H. Erickson, et al.

Serial No. : 09/927,225

Filed : August 10, 2001

For : STIMULATING/SENSING LEAD ADAPTED FOR PERCUTANEOUS INSERTION

Group No. : 3762

Examiner : F.P. Oropeza

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

DECLARATION OF PRIOR INVENTION UNDER 37 C.F.R. 1.131

1. This declaration is to establish prior invention in this application in the United States (or a NAFTA or WTO country), at a date prior to February 13, 2001, that is the effective date of the reference (United States Patent No. 6,522,932) cited by the U.S. Patent and Trademark Office (in Office Action having a mailing date of July 26, 2004).

2. The persons making this Declaration are the inventors, John H. Erickson, Scott F. Drees, Terry Daglow and John Cornell Munson, Jr.

3. To establish the date of the invention of this application, the following attached documents are submitted herewith as evidence: Invention disclosure pages (2 pages).

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PATENT**

4. The invention in this application was (1) reduced to practice at least as early as February 13, 2001, which is prior to the effective date of the reference; and/or (2) was conceived at least as early as February 13, 2001, which is prior to the effective date of the reference, coupled with due diligence from prior to the effective date of the reference to a subsequent reduction to practice or to the filing of the application. Upon information and belief, the effective date of the reference is February 13, 2001 and this application was filed on August 10, 2001 (approximately less than six months after the effective date of the reference) which evidences due diligence from prior to the effective date of the reference to the filing of this application.

5. Upon information and belief, this Declaration is being submitted prior to final rejection.

6. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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ATTORNEY DOCKET NO. 02-007CIP (ANSI01-00057)
U.S. SERIAL NO. 09/927,225
PATENT

SIGNATURE:

Inventor: John H. Erickson

Inventor Residence: 3516 Interlaken Dr
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Inventor Country of Citizenship: USA

Inventor Signature: John H. Erickson

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Inventor Country of Citizenship: USA

Inventor Signature: Scott F. Drees

Inventor: Terry Daglow

Inventor Residence: 1005 Ashland Ct
Allen, TX 75013

Inventor Country of Citizenship: USA

Inventor Signature: Terry Daglow

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U.S. SERIAL NO. 09/927,225
PATENT****Inventor:** John Cornell Munson, Jr.**Inventor Residence:**1315 High Ridge Farms Dr
McKinney, TX 75069**Inventor Country of Citizenship:**U.S.**Inventor Signature:**John C. Munson, Jr.

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INVENTION DISCLOSURE INFORMATION FORM

ID NUMBER 0023

TECHNICAL FIELD—*In the broadest of terms, describe the invention.*

Neuro-stimulation lead and implant system.

PROBLEM—*What condition or circumstance prompted the invention? How did existing products or devices fall short of addressing the condition or circumstance?*

To implant a Surgical Lead today requires a laminectomy or laminotomy. Doctors would like the efficacy benefits of the Surgical Lead with the implant ease of a Percutaneous Lead.

PRIOR ART—*Identify all products in the U.S. marketplace, articles, written materials, and any known patented inventions which are, generally or specifically, similar to the invention.*

See Percutaneous and Surgical Lead Prior Art.

Number of Additional Pages:

INVENTION—*Describe the invention in detail. Attach any sketches of the invention and/or copies of all design/engineering notebook pages.*

This invention is a stylet steerable, two or more electrode, electric field directional, neuromodulation stimulation lead and implant accessories. The stylet consisting of a wire with a handle, the wire to be straight or to have one or more bends. The stylet when inserted into the inner lumen, the entire length of the lead, will provide a stiffing member for handling and placement. A stylet with multiple bends would allow a side to side or forward motion of the lead when rotated clockwise or counter clockwise inside the lead. The lead would consist of a stimulation paddle, two or more electrodes, and a terminal end (mechanical and electrical connector). The stimulation paddle is constructed of a varying cross sectional moment of inertia, allowing ease of bending when inserted with a stylet, see attached. The stimulation paddle height is to be approximately one half of the paddle width. The electrodes are placed on one side of the paddle to create an uni-directional electric field. The electrode side of the paddle is placed directly over the stimulation site. The lead can be placed or directed to the implant site by the use of a modified epidural needle and/or a dilating catheter. The needle consists of a canula and a stylet, see attached. The canula has an inside cross section to match the lead paddle and a stylet to prevent tissue coring. The dilating catheter would be inserted over a guide wire, previously placed through an epidural needle, to the desired location, the inner lumen removed and replaced with the lead.

Number of additional pages/drawings: 5

BENEFITS/NOVELTY—*Describe the benefits of the invention over the prior art, and state generally what feature(s) of the invention that you consider to be new.*

1. This is a surgical lead capable of being placed percutaneously. 2. The varying cross section allows for flexibility when used in conjunction with a stylet, straight or bent. 3. The use of a stylet with one or more bends to allow side to side or linear motion when rotated inside the lead body. 4. Offers two introduction methods, modified epidural needle or dilating catheter. 5. Uni-directional electrode stimulation, similar to current laminotomy electrode.

Number of additional pages/drawings:

PREVIOUS OR PLANNED DISCLOSURES—*Specifically identify and list any disclosure, or planned disclosure, of the invention to the public, for example, through sale, use, offer to sell, show or display.*

Date invention was first conceived: Unknown

Date of first written description/sketches:

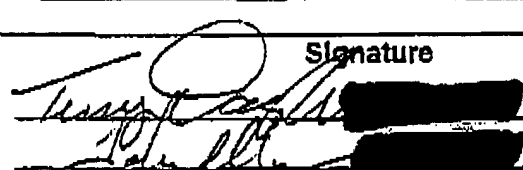
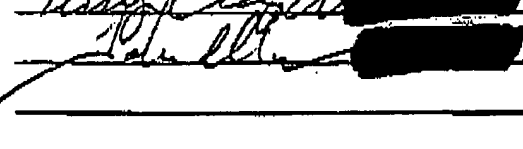
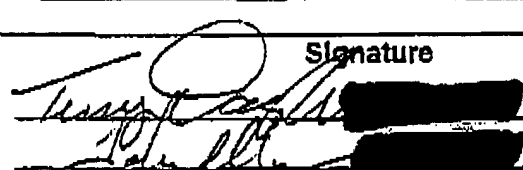
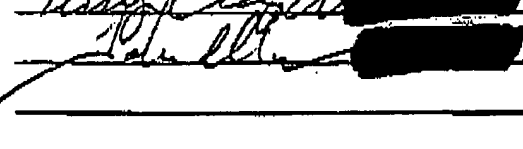
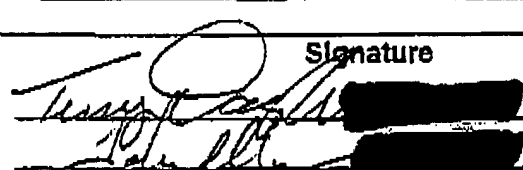
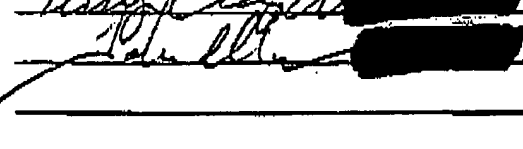
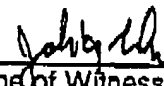
Date invention was first disclosed:

To whom was the invention disclosed: Reno Lauro

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INVENTION DISCLOSURE INFORMATION FORM

<p>Has Invention been tested experimentally or prototyped? <input checked="" type="checkbox"/> YES or <input type="checkbox"/> NO</p> <p>If YES, date [redacted] and performed by: John Munson</p> <p>EXPERIMENT or <input checked="" type="checkbox"/> PROTOTYPE</p>	<p>Has Invention been disclosed to persons outside the company (e.g., vendors, clients, customers, etc.)? <input checked="" type="checkbox"/> YES or <input type="checkbox"/> NO</p> <p>If YES, date [redacted] to whom: [redacted]</p> <p>How? Prototype Lead</p>																				
<p>When did/does commercial use begin? [redacted]</p> <p>Other:</p> <p>See attached note book entries.</p> <p>Number of Additional Pages: 3</p>																					
<p>NAME OF THE INVENTOR(S), WITH SIGNATURES</p> <table style="width: 100%;"><thead><tr><th style="width: 50%; text-align: center;">Name</th><th style="width: 50%; text-align: center;">Signature</th></tr></thead><tbody><tr><td>Terry Daglow</td><td></td></tr><tr><td>John Connell Munson Jr.</td><td></td></tr><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></tbody></table>		Name	Signature	Terry Daglow		John Connell Munson Jr.															
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<p>HOME ADDRESS OF EACH INVENTOR:</p> <table style="width: 100%;"><thead><tr><th style="width: 50%;">Name: Terry Daglow</th><th style="width: 50%;">Name:</th></tr></thead><tbody><tr><td>Address: 1005 Ashland Ct.</td><td>Address:</td></tr><tr><td> </td><td> </td></tr><tr><td>City: Allen State: TX</td><td>City: State:</td></tr><tr><td>Zip: 75013</td><td>Zip:</td></tr><tr><td>Name: John Connell Munson Jr.</td><td>Name:</td></tr><tr><td>Address: 1315 Highridge Farms Rd.</td><td>Address:</td></tr><tr><td> </td><td> </td></tr><tr><td>City: McKinney State: TX</td><td>City: State:</td></tr><tr><td>Zip: 75069</td><td>Zip:</td></tr></tbody></table>		Name: Terry Daglow	Name:	Address: 1005 Ashland Ct.	Address:			City: Allen State: TX	City: State:	Zip: 75013	Zip:	Name: John Connell Munson Jr.	Name:	Address: 1315 Highridge Farms Rd.	Address:			City: McKinney State: TX	City: State:	Zip: 75069	Zip:
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<p>I have read and understood the above invention description, including any additional pages attached here, and witnessed the subscribing of the above signature(s).</p> <p style="text-align: right;">1 4 1 5</p>																					
<p></p> <p>Name of Witness</p>	<p>[redacted]</p> <p>Date</p>																				